



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,847	12/05/2003	William Alston	0138.00	8316

21968 7590 08/21/2007
NEKTAR THERAPEUTICS
150 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER

ALI, SHUMAYA B

ART UNIT	PAPER NUMBER
----------	--------------

3771

MAIL DATE	DELIVERY MODE
-----------	---------------

08/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/729,847
Filing Date: December 05, 2003
Appellant(s): ALSTON, WILLIAM

MAILED

AUG 21 2007

Group 3700

Mr. Guy V. Tucker
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/8/07 appealing from the Office action mailed 10/11/06.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct with respect to whether the rejection to claims 1-7, and 10-17 under 35 USC 102(b) as being anticipated by Dean et al. US 4,249,526 is proper, and (3) the rejection to claims 8,9,18, and 19 under 35 USC 103(a) as being obvious over either singly with Dean et al. US 4,249,526 or in view of Chiprich et al. US 5,614,217 is proper

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. Examiner agrees that claim 4 and 14 meet the requirements under 35 USC 112, second paragraph, thus, withdraws said rejection.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,249,526	Dean et al.	02-1981
5,614,217	Chiprich et al.	03-1997

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 10-17, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Dean et al. US Patent No. 4,249,526

As to claim 1, Dean et al discloses an aerosolization apparatus comprising: a body (fig.1, 1) defining an inlet opening (fig.1, 11/12), an outlet opening (toward the mouthpiece, fig.1, 5),

and an aerosolization chamber (fig.2, 15) between the inlet opening and the outlet opening, wherein the aerosolization chamber is adapted to receive an elongated receptacle (fig.2, 24) containing a pharmaceutical formulation (col.2 lines 1-8) and wherein the elongated receptacle rotates, an axis end-over-end about an axis substantially orthogonal to an axis passing through the outlet opening when air or gas flows through the body (2-fold axis of symmetry reads on end-over-end, see col.4 lines 32-38, figs.3 and 4).

As to claim 2, Dean et al. discloses an aerosolization apparatus according to claim 1 further comprising an opening mechanism (see fig.1, 20) for creating an opening in the receptacle.

As to claim 3, Dean et al. discloses an aerosolization apparatus according to claim 2 wherein the opening mechanism comprises a sharpened tip (pins with sharp tips as depicted in fig.1, 20) moveable within the aerosolization chamber (col.4 lines 15-35).

As to claim 4, Dean et al. discloses an aerosolization apparatus according to claim 1 further comprising the receptacle (see fig.2)

As to claim 5, Dean et al. discloses an aerosolization apparatus according to claim 4 wherein the receptacle comprises a capsule (fig.2, 24).

As to claim 6, Dean et al. disclose an aerosolization apparatus according to claim 5 wherein the capsule comprises a wall comprising one or more of gelatin, hydroxypropyl methylcellulose, polyethyleneglycol-compounded hydroxypropyl methylcellulose, hydroxypropylcellulose, and agar (col.2 lines 1-8).

As to claim 7, Dean et al. discloses an aerosolization apparatus according to claim 5 wherein the receptacle contains a powder pharmaceutical formulation (col.1 lines 25-29).

As to claim 10, Dean et al. discloses an aerosolization apparatus for delivering an aerosolized pharmaceutical formulation to a user's respiratory tract, the apparatus comprising: a body (fig.1, 1) defining an inlet opening (fig.1, 11), an outlet opening (toward the mouthpiece, fig.1, 5), and an aerosolization chamber (see fig.2, 15) between the inlet opening and the outlet opening, wherein the aerosolization chamber is adapted to receive an elongated receptacle (see fig.2, 24) containing a pharmaceutical formulation (col.2 lines 1-8), an axis (parallel to a longitudinal axis of the apparatus), wherein the elongated receptacle rotates end-over-end about an axis substantially orthogonal to an axis parallel to an inhalation direction when the user inhales to cause air or gas to pass through the body (2-fold axis of symmetry reads on end-over-end, see col.4 lines 32-38, figs.3 and 4).

As to claim 11, Dean et al. discloses an aerosolization apparatus according to claim 10 wherein the inhalation direction is a direction coincident with an axis passing through a mouthpiece (fig.1, 3) of the apparatus.

As to claim 12, Dean et al. discloses an aerosolization apparatus according to claim 10 further comprising an opening mechanism (see fig.1, 20) for creating an opening in the receptacle.

As to claim 13, Dean et al. discloses an aerosolization apparatus according to claim 12 wherein the opening mechanism comprises a sharpened tip (pins with sharp tips as depicted in fig.1, 20) moveable within the aerosolization chamber (col.4 lines 15-35).

As to claim 14, Dean et al. discloses an aerosolization apparatus according to claim 10 further comprising the receptacle (see fig.2).

As to claim 15, Dean et al. disclose an aerosolization apparatus according to claim 14 wherein the receptacle comprises a capsule (col.2 lines 1-7).

As to claim 16, Dean et al. disclose an aerosolization apparatus according to claim 15 wherein the capsule comprises a wall comprising one or more of gelatin, hydroxypropyl methylcellulose, polyethyleneglycol-compounded hydroxypropyl methylcellulose, hydroxypropylcellulose, and agar (col.2 lines 1-8).

As to claim 17, Dean et al. disclose an aerosolization apparatus according to claim 15 wherein the receptacle contains a powder pharmaceutical formulation (col.1 lines 25-29).

As to claim 20, Dean et al. disclose an aerosolization apparatus according to claim 10 wherein the inlet opening is shaped to cause a swirling air or gas flow through the chamber (col.4 lines 30-38).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 3771

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dean et al. US Patent No. 4,249,526.

As to claim 8, Dean et al. does not disclose an aerosolization apparatus according to claim 7 wherein the powder pharmaceutical formulation comprises particles having a mass median diameter less than 10 um. A close review of the applicant's discloser reveals "a particle size selected to permit penetration into the alveoli of the lungs" (see specification page 14, lines 26-27). The mass median diameter will vary depending on the releasing site/the type of tissue absorbing that medication. Therefore, the Mass median diameter can be made smaller or larger to respectively increase or decrease the absorbent nature of tissue, and tissue can vary from patient to patients. Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to manipulate the mass median diameter of pharmaceutical formulation particles because doing so would have allowed treatment depending on patient's tissue absorbent efficiency.

As to claim 18, Dean et al. discloses claimed invention as applied to claim 8.

Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dean et al. US Patent No. 4,249,526 and in view of Chiprich et al. US Patent 5,614,217

As to claim 9, Dean et al. does not disclose an aerosolization apparatus according to claim 7 wherein the powder pharmaceutical formulation has moisture content below 5% by

Art Unit: 3771

weight. A close review of the disclosure reveals that the applicant prefers a moisture content below about 10% by weight, usually below about 5% by weight, and preferably below about 3% by weight, also discloses such powder are described in the prior art (see specification page 15, lines 2-4). A range of moisture content (below 10%-below about 3%) presented by the applicant is recognized, however the applicant has not established why a moisture content of 10% or 3% by weight would be critical to the invention. Chiprich et al. in a capsule shell formulation teach a brittle gelatin capsule comprises about 5-15% water by weight to provide a finished capsule which remains breakable with manual pressure in changing environmental conditions without the need of special treatments or moisture resistant packaging (col.1 lines 55-60 and col.2 lines 51-55). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the capsule of Dean et al. in view of Chiprich in order to provide a moisture content of 5-15% because doing so would have allowed breakable of capsule with manual pressure in changing environmental conditions without the need of special treatments or moisture resistant packaging.

As to claim 19, Dean et al. disclose claimed invention as applied to claim 9.

(10) Response to Argument

The rejection of independent claim1 under 35 USC 102 (b) is improper

Applicant's argument with respect to a receptacle (24) in the aerosolization chamber (15) of Deal et al rotates about an axis that is parallel to the axes passing though the outlet opening (5) of Deal et al. Thus, Deal et al. does not disclose a chamber wherein a receptacle would rotate about an axis that is orthogonal to the axis of the outlet opening (see appeal brief filed on 6/8/07, page 4, lines 5-9) have been fully considered but they are not persuasive.

First, Deal et al. discloses an apparatus that is identical to the claimed apparatus (see labeled figure 1 of Dean et al. and 1E of Applicant's invention attached below). Under the "Summary of the Claimed Subject Matter" Applicant points out his claimed structures (see appeal brief filed on 6/8/07, page 2), which are also labeled in the attached figure 1E. In applicant's invention, air is drawn into a chamber (110) through two air inlet openings (115) to cause a receptacle (125) to rotate end-over-end about an axis substantially orthogonal to an axis passing through an outlet opening (125). Dean et al. as well discloses two air inlet openings (11,12), which draw air into a chamber (15) to cause a receptacle (24) to rotate about its 2-fold axis of symmetry (see col.4, lines 15-38). Rotation about 2-fold axis of symmetry renders that Dean et al. receptacle is fully capable of rotating end-over-end. Although, Dean et al. is silent on rotation about an axis substantially orthogonal to an axis passing through an outlet opening, disclosing an aerosolization apparatus that is identical to Applicant's invention and given the fact that Applicant has not identified any structural distinction that would allow his apparatus to function differently, one of ordinary skill in the art would expect Dean et al. receptacle to rotate as claimed.

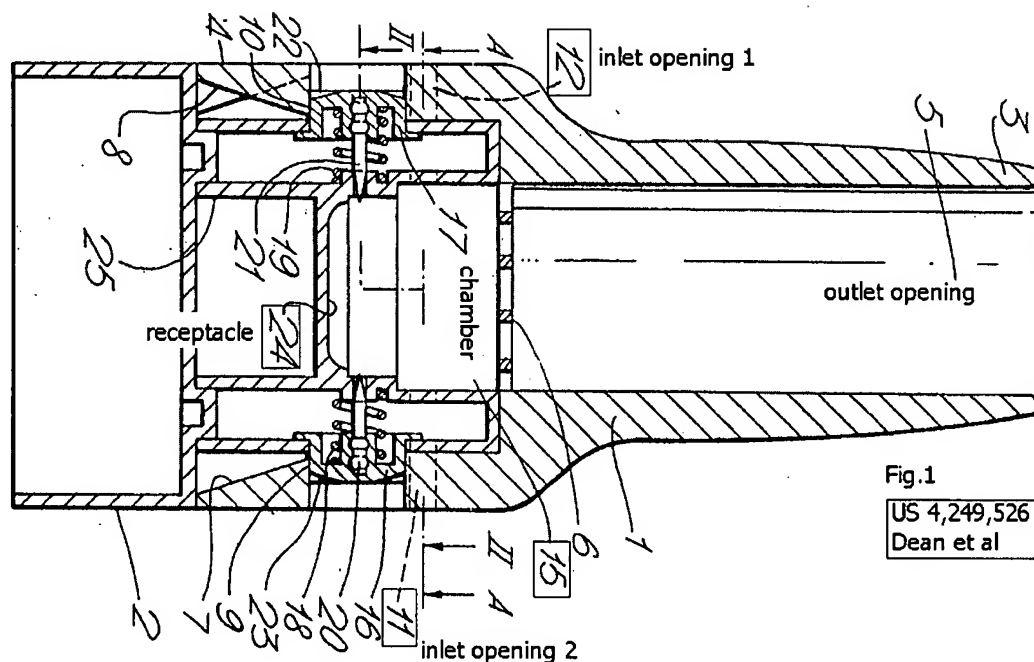


Fig. 1

US 4,249,526
Dean et al

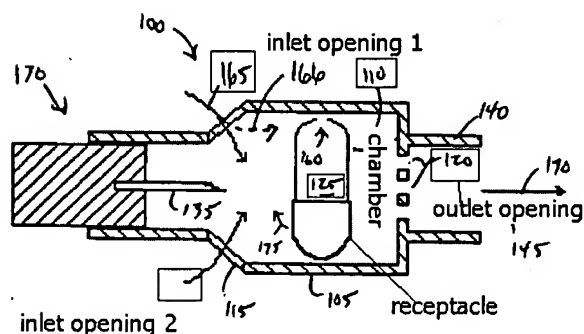


Fig. 1E

Applicant's invention

Second, during operation, a user has to hold the apparatus at a location distal to the outlet opening, thus, during the process of inhalation, it is likely that a user may block one of the air inlet openings. Therefore, when the user holds the inhaler such that he/she covers one of the inlet openings (11), inhalation suction force would cause air to enter through the other inlet (12). Air coming in from only one inlet would turn/rotate the receptacle toward the direction of the airflow/outlet opening. Thus, a receptacle that is lifted and turned from a position perpendicular

Art Unit: 3771

to the outlet opening to a direction of the outlet opening would inherently acquire a rotational axis that is orthogonal to the axis of the outlet opening.

Last, claimed rotational limitation is recited as part of the intended use of the apparatus. Deal et al. apparatus is fully capable of meeting such indented use recitation. Note, Deal et al. never stated that his receptacle must meet certain size. The receptacle rotational axis would depend on the size of the receptacle as well as the chamber. Thus, a receptacle small enough, say for example, one third the size of the receptacle depicted in figure 2 of Dean et al., can be adapted to the chamber of Dean et al., which will provide the receptacle with enough space to rotate at any axis including an axis that is orthogonal to the outlet opening.

In further argument, Applicant was concerned that Examiner's position on the "2-fold axis of symmetry" and how it reads on claimed end-over-end rotation is unclear (see appeal brief filed on 6/8/07, page 4, lines 10-13. Above discussion should address Applicant's concern.

Applicant argues that claims 2-9 depend from claim 1 and are also not anticipated by Dean et al (see appeal brief filed on 6/8/07, page 4, line 26), however, Applicant does not state why claims 2-9 are not anticipated by Deal et al. Examiner asserts that Applicant believes since claim 1 is not anticipated by Dean et al., claim depending from claim 1 are also not anticipated by Dean et al. However, as reasoned above, Deal et al. fully anticipates the subject matter of claim 1.

The rejection of independent claim 10 under 35 USC 102 (b) is improper

With respect to claim 10, Applicant argues, "claim 10 is similar to Appellant's independent claim 1, which the exception that "axis passing through the opening" is replaced with "axis parallel to an inhalation direction"...The receptacle in Dean et al. clearly does not rotate

Art Unit: 3771

about such an axis and therefore does not anticipate claim 10” (see appeal brief filed on 6/8/07, page 4, lines 28-30 and page 5, lines 1 and 2), this argument however is not well taken. Since Applicant admits that the two axis are same and no other distinction found between claim 1 and claim 10, Dean et al. anticipating the limitation of claim 1 as discussed above also anticipate the limitation of claim 10.

The rejection of claims 8,9,18, and 19 under 35 USC 103(a) is improper

With respect to claims 8,9,18, and 19, Applicant argues, “the Examiner does not suggest that it would have been obvious to modify the rotational arrangement of Dean et al (nor would it be)...Chiprich et al. also fails to disclose or suggest the necessary rotational arrangement and is of no movement in this consideration. Accordingly claims 8,9, 18 and 19 are not rendered unpatentable by Dean et al. or by Dean et al. in combination with Chiprich et al” (see appeal brief filed on 6/8/07, page 5, lines 5-14), however, such argument is not well taken because (1) Examiner did provide adequate 103 obviousness reasoning (see above rejection cited for claims 8,9,18, and 19) and (2) Chiprich et al. reference was used to teach pharmaceutical formulation and claimed percent weight, not the rotational arrangement (see rejection for claims 9 and 19 cited above). Thus, claims 8,9,18, and 19 rendered unpatentable by Dean et al. or by Dean et al. in combination with Chiprich et al.

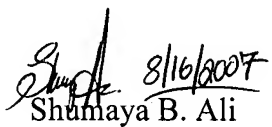
(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner’s answer.

For the above reasons, it is believed that the rejections should be sustained.

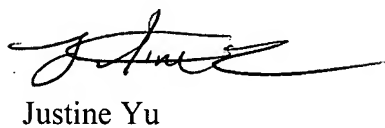
Respectfully submitted,

Art Unit: 3771


Shumaya B. Ali

Conferees:


Janet Baxter


Justine Yu

JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700